UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

STACEY STEWART-MACKEY, individually and as Administrator of the Estate of Rachel Sweet,	*	
Plaintiff,	*	
v.	*	Civil Action No. 23-cv-10155-ADB
CORCYM, INC.,	*	
Defendant.	*	

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Plaintiff Stacey Stewart-Mackey ("Plaintiff") brings this personal injury case on behalf of herself and as administrator of the estate of Rachel Sweet ("Rachel") pursuant to Mass. Gen. Laws Ch. 229, § 2 *et seq*. Plaintiff generally alleges that Defendant Corcym, Inc.'s ("Defendant" or "Corcym") faulty medical device was responsible for Rachel's untimely death. See generally [ECF No. 1 ("Complaint" or "Compl.")]. Now pending before the Court is Defendant's motion to dismiss all claims. [ECF No. 10]. For the reasons set forth below, the motion is GRANTED.

I. BACKGROUND

A. Factual Background

The following relevant facts are taken primarily from the Complaint, which the Court assumes to be true when considering a motion to dismiss. Ruivo v. Wells Fargo Bank, N.A., 766 F.3d 87, 90 (1st Cir. 2014).

Defendant owns the company that made the Sorin Mitroflow Aortic Health Valve (the "Valve"). [Compl. at 1; id. ¶¶ 24–26]. Rachel was implanted with the Valve around 2013, when

she was thirteen years old, with the hope that it would support her growth for the next 10 to 20 years. [Id. ¶¶ 5, 6, 67; ECF No. 11 at 4].

Plaintiff alleges that, prior to Rachel's implant, the company producing the Valve should have known that it was faulty and causing damage to recipients, see [Compl. ¶¶ 37–38], namely calcification and tissue deterioration, [id.], but that it was concealing this knowledge from the FDA, [id. ¶¶ 38–39]. In any event, after a 2014 study, "physicians recommended against using the Valve," and the manufacturer "finally addressed" the "deterioration/calcification problem via a *de facto* recall, removing the Valve from circulation," and "replacing" it with a new model. [Id. ¶ 40].

In 2015, Rachel began experiencing complications with the Valve, and it was determined that it needed to be replaced with a larger valve. [Compl. ¶¶ 9–15]. During the ensuing surgery, rather than receiving a larger valve, Rachel received a new valve that was the same size because the damage caused by the original Valve made using a larger replacement impossible. [Id. ¶¶ 13–14]. "Because Rachel was forced to accept" the same size valve, "her options for any future intervention became limited," including that she could not receive a transcatheter aortic valve replacement (TAVR), which meant that future surgeries would require opening her sternum. [Id. ¶ 16].

Over the next five years, Rachel "appeared to be doing okay," and "[a]lthough she was in and out of the hospital, she managed a relatively normal life." [Compl. ¶ 17]. "There was no indication [she] was suffering after her" surgery to replace the Valve. [Id. ¶ 18].

Then in December 2020, Rachel had an episode of atrial fibrillation that lasted a month. [Compl. ¶ 19]. She was admitted to the hospital in January 2021 and learned she was experiencing heart failure and that she needed a larger valve, which she couldn't get because of

the prior damage caused by the original Valve. See [id. ¶¶ 16, 20–22]. Additionally, she was not strong enough to have her sternum opened again. [Id. ¶ 22]. "With no options available, Rachel died on May 1, 2021." [Id. ¶ 23].

B. Procedural History

Plaintiff filed the Complaint on January 24, 2023, asserting claims for negligence, design defect, failure to warn, breach of warranty, gross negligence/wrongful death, and violation of Mass. Gen. Laws Ch. 93A. [Compl. at 1]. Defendant moved to dismiss on March 17, 2023, [ECF No. 10], Plaintiff opposed on April 17, 2023, [ECF No. 14], and Defendant replied on April 27, 2023, [ECF No. 18].

On July 7, 2023, Defendant filed a notice of supplemental authority, [ECF No. 19], notifying the Court of a Massachusetts Supreme Judicial Court decision, Fabiano v. Philip Morris USA Inc., 211 N.E.3d 1048 (Mass. 2023), which bears on the issue of whether the statute of limitations has run on Plaintiff's claims. See id. at 1055–56.

II. STANDARD OF REVIEW

Under Rule 12(b)(6), a complaint "must provide 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" Cardigan Mountain Sch. v. N.H. Ins. Co., 787 F.3d 82, 84 (1st Cir. 2015) (quoting Fed. R. Civ. P. 8(a)(2)). This pleading standard requires "more than labels and conclusions," Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007), and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Rather, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. (quoting Twombly, 550 U.S. at 570).

III. DISCUSSION

A. Statute of Limitations

In Massachusetts, "any claim brough under" the wrongful death statute is "tied" to or derivative of "the decedent's action." Fabiano, 211 N.E.3d at 1054 (internal quotations omitted) (citing GGNSC Admin. Servs., LLC v. Schrader, 140 N.E.3d 397, 404 (Mass. 2020)). Thus, "[w]here a decedent had no right on the date of his or her death to bring suit for the injury that caused his or her death, no cause of action for wrongful death based on the death-causing injury ever vests in the decedent's representative for the benefit of the beneficiaries," Fabiano, 211 N.E.3d at 1056, and "recovery [is precluded] for wrongful death where the statute of limitations on the decedent's underlying claims ran before the decedent's death," id. at 1059.

A cause of action for breach of warranty and/or tort accrues "when a plaintiff discovers, or any earlier date when she should reasonably have discovered, that she has been harmed or may have been harmed by the defendant's conduct." Bowen v. Eli Lilly & Co., Inc., 557 N.E.2d 739, 741 (Mass. 1990); see also Fidler v. Eastman Kodak Co., 714 F.2d 192, 197 (1st Cir. 1983) (finding discovery rule also applies to breach of warranty claims); Sheedy v. Deutsche Bank Nat'l Tr. Co. (In re Sheedy), 801 F.3d 12, 20 (1st Cir. 2015) (citing Bowen). This "discovery rule" is also applicable to Chapter 93A actions. Monteferrante v. Williams-Sonoma, Inc., 241 F. Supp. 3d 264, 271 (D. Mass. 2017) (citing Cambridge Plating Co. v. NAPCO, Inc., 991 F.2d 21, 25 (1st Cir. 1993)).

Under the discovery rule, "[t]he plaintiff need not know the full extent of the injury before the statute starts to run." Bowen, 557 N.E.2d at 741 (citing Olsen v. Bell Telephone Laby's, Inc., 445 N.E.2d 609, 612–13 (Mass. 1983). Rather, "[t]he important point is that the

statute of limitations starts to run when an event or events have occurred that were reasonably likely to put the plaintiff on notice that someone may have caused her injury."

"Where compliance with a statute of limitations is at issue, 'factual disputes concerning when a plaintiff knew or should have known of his cause(s) of action are to be resolved by the jury.'" Patsos v. First Albany Corp., 741 N.E.2d 841, 847 (Mass. 2001) (quoting Riley v. Presnell, 565 N.E.2d 780 (Mass. 1991)). That said, although "the question of when a plaintiff should have known and when a plaintiff should have asserted her rights, are questions of fact," the court may consider the statute of limitations defense on a motion to dismiss if "the facts regarding discovery of harm are undisputed." See Stanley v. Schmidt, 369 F. Supp. 3d 297, 314–15 (D. Mass. 2019) (quoting Mass. Hous. Opportunities Corp. v. Whitman & Bingham Assocs., P.C., 983 N.E.2d 734, 737 (Mass. App. Ct. 2013)); see also Arcieri v. N.Y. Life Ins. Co., 63 F. Supp. 3d 159, 163, 165 (D. Mass. 2014) (granting motion to dismiss negligence and 93A claim because the limitations period had run) (citing Santana-Castro v. Toledo-Dávila, 579 F.3d 109, 113–14 (1st Cir. 2009)).

Here, Plaintiff does not dispute that if the injury was discovered or reasonably should have been discovered in 2015 at the time of Rachel's initial valve replacement, the statute of limitations would have run before the Complaint at issue here was filed in January 2023. See [ECF No. 11 at 9–12, 12 n.9; ECF No. 14 at 3–5].

Defendant argues that "the failure to warn the FDA about adverse events associated with the [Valve]; and Rachel's alleged injury, i.e., the [damage caused by] the [Valve] and its removal in 2015, serve as the basis for all claims." [ECF No. 11 at 9]. Thus, Plaintiff "knew or should have known of the alleged connection between Rachel's injuries and the [Valve], and had a duty

to investigate any potential claims to recover for those injuries beginning at least in 2015." [Id. at 10–11].

In contrast, Plaintiff argues that "Rachel did not know of, or begin to suffer, the deadly effects caused by the valve until December 2020," [ECF No. 14 at 3], when she began to experience atrial fibrillation, see [Compl. ¶ 19]. More specifically, Plaintiff "alleges unequivocally that Rachel did not begin to suffer the personal injuries (heart failure) that led to her untimely death until December 2020," and that on a motion to dismiss, "[i]t must be taken as fact" that "Rachel recovered nicely after the 2015 surgery," and "went on to live a relatively normal life" without "indications that [she] would suffer a premature death." [ECF No. 14 at 3–4]. Although Plaintiff acknowledges that "there were known problems with the [] [V]alve when it was removed," it argues that "it takes a giant leap to assert that Rachel and her family 'knew or should have known of the alleged connection between Rachel's injuries and the [Valve], and had a duty to investigate any potential claims to recover for those injuries beginning at least in 2015.'" [Id. (quoting ECF No. 11 at 11)].

Plaintiff's own allegations, however, belie current claims of a lack of knowledge. According to Plaintiff, (1) by 2014, the Valve had been removed from circulation due to the same injuries—calcification and deterioration—that it caused for Rachel, see [Compl. ¶¶ 13, 15, 40]; (2) the "goal" of the 2015 surgery was to replace the Valve "with a larger one that would accommodate her growing body," which they could not do as a result of the faulty Valve, [id. ¶ 13]; and (3) "because Rachel was forced to accept [the same size] valve, her options for any future intervention became limited," [id. ¶ 16].[1] Based on these assertions, in 2015, Plaintiff was

[1] Although Plaintiff claims in its motion that Rachel's personal injury was heart failure, [ECF No. 14 at 3 ("Rachel did not begin to suffer the personal injuries (heart failure) . . . until

already aware of the injury and the fact that her options for future treatment would be limited. The fact that the limited treatment options caused by the Valve did not result in her death until 2020 does not toll or change the statute of limitations. See Olsen, 445 N.E.2d at 612–13 (granting summary judgment on statute of limitations grounds, finding that the "argument that a claim for permanent injury accrues only when the permanency is, or should have been discovered, would create an unacceptable imbalance between affording plaintiffs a remedy and providing defendants the repose that is essential to stability in human affairs. If knowledge of the extent of injury were to control the accrual of a cause of action, the fixed time period of statutes of limitations effectively would be destroyed. The full extent of an injury often is not discoverable for many years after it has been incurred."); Cuddy v. Philip Morris USA Inc., No. 1784CV02213, 2021 WL 6880839, at *2 (Mass. Super. Ct. Oct. 5, 2021) (granting motion to dismiss on statute of limitations grounds where Plaintiff, who died in 2014, "was aware of the link between his smoking history and his [disease] at or around the time of his diagnosis," and thus "any breach of warranty or tort claim that [he] may have had against Defendants on account of his smoking-related injuries began to run in 2004."). Accordingly, Plaintiff was aware of the

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December 2020")], the Complaint confirms that the injury underlying Plaintiff's claims is the deterioration/calcification of the Valve. For example, in the introduction to the Complaint, Plaintiff states that "Plaintiff brings [] claims arising out of the Valve manufacturer's failure to update and to report . . . [its] knowledge of events concerning the rapid premature bovine tissue deterioration/calcification in Valve recipients." [Compl. at 1]. It then specifically alleges that, for example, "severity of the calcification in and around the Valve would limit the size of any new valve," [id. ¶ 13]; the Valve was "explanted [in 2015] . . . due to . . . extensive intrinsic leaflet calcification," [id. ¶ 15]; Defendant improperly concealed the Valve's "heightened propensity for early deterioration/calcification," [id. ¶ 32]; see also [id. ¶¶ 35–36, 49, 68–69, 83, 101 (similar)]; and that had the risks been properly disclosed, "the Valve would not have been selected for use by Rachel . . . and the Valve's failure, leading to Rachel's death, would not have occurred," [id. ¶ 42]. In fact, heart failure is mentioned in the Complaint just once without any allegation that it was caused by the Valve. [Id. ¶ 21 ("Over the next four months (all inpatient), it became evident that Rachel was experiencing heart failure.")].

alleged injury in 2015, and the statute of limitations had run by the time she brought suit in 2023. See [ECF No. 11 at 9–12, 12 n.9; ECF No. 14 at 3–5].

B. Preemption

Defendant next argues that, even if the claims were not barred by the applicable statutes of limitations, they are preempted under federal law. [ECF No. 11 at 13–16].

The parties agree that the same preemption issue here was "previously litigated in this Court" in Plourde v. Sorin Group USA, Inc., No. 17-cv-10507-ADB. [Compl. at 1]; see also [ECF No. 11 at 14 ("this Court considered the question of whether a nearly identical set of claims was preempted in the Plourde matter"); ECF No. 14 at 9 ("Plaintiff's claims in this case are identical to those asserted in Plourde.")]. There, this Court found on summary judgment that plaintiffs had not "identified a specific duty to report to the FDA under Massachusetts law," and that plaintiffs' claims were therefore preempted. Plourde, 517 F. Supp. 3d 76, 87–92 (D. Mass. 2021).

On appeal, the First Circuit, similarly finding that the caselaw provided "no definitive guidance" on the pertinent state law question, certified the following question to the Massachusetts Supreme Judicial Court ("SJC"): "Does a manufacturer's failure to report adverse events to a regulator – such as one like the FDA – give rise to liability under Massachusetts law?" Plourde, 23 F.4th 29, 36–37 (1st Cir. 2022). Before the SJC could answer the question, however, the appeal was voluntarily dismissed and the order certifying the question was vacated as moot. Id., No. 21-1145 (Feb. 1, 2022).

The Court finds no basis to reach a different conclusion than it did in Plourde, and because dismissal is appropriate here on statute of limitations grounds, it declines at this stage to certify to the SJC the question previously certified by the First Circuit.

IV. CONCLUSION

Accordingly, Defendant's motion to dismiss, [ECF No. 10], is GRANTED.

SO ORDERED.

October 26, 2023

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE